JAN 2008

K071608

Chapter 04 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____.

Submitter:

Zhongshan A & J Medical Equipment CO., LTD

Address: No.3 Shenghui South Road Nantou Town, Zhongshan, City, Guangdong CHINA P.R.C

- **Contact Person:**

Polo Chen R&D Manager
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Applicant: Zhongshan A & J Medical Equipment CO., LTD

Address: No.3 Shenghui South Road Nantou Town, Zhongshan, City, Guangdong CHINA P.R.C

- **Date Prepared:**

January 15, 2007

Name of the device:

- **Trade/Proprietary Name:** The A&J-POCA01 Oxygen Concentrator
- **Common Name:** Oxygen Concentrator
- **Classification**

21 CFR 868.5440	Portable Oxygen Generator	Class II

Legally Marketed Predicate Device:

K032509 Mark 5 Nuvo Oxygen Concentrator

Description:

The A&J-POCA01 Oxygen Concentrator is intended for use as an oxygen concentrator to provide supplemental low flow oxygen therapy in the home, nursing homes, patient care facilities, etc. The A&J-POCA01 is available by prescription only under the supervision of a physician, and is not intended to support or sustain life.

The A&J-POCA01 is an AC power electrically operated. The unit separates oxygen from room air (ambient air) which allows high-purity supplemental oxygen to be delivered through the oxygen outlet, although the concentrator filters the oxygen in a room, it will not affect the normal amount of oxygen in your room. Air is drawn into the device with a compressor and exposed to molecular sieve adsorbent that selectively retains nitrogen and other components until they are released when the pressure is vented to the atmosphere. This cycle is controlled by a motorized value and protected from over pressurization by the compressor's pressure relief value.

Oxygen provided by the A&J-POCA01 Oxygen Concentrator is delivered to the user by means of standard oxygen supply tubing and a standard nasal cannula or mask. A standard bubble humidifier may be used, if physician has prescribed an oxygen humidifier as part of therapy.

The front panel of the A&J-POCA01 contains the controls and indicators. These include the status lights (included power light, normal oxygen light, low oxygen light and service required light), standard power switch, flow meter and the flow meter knob, a circuit breaker which could reset the device after electrical overload shutdown, a oxygen outlet which oxygen is dispersed through, a monitor display which indicates the condition of system status (included pressure status, oxygen purity status and electric hour meter, etc). The user could operated the device conveniently according the instructions.

Statement of intended Use:
The A&J-POCA01 Oxygen Concentrator is intended for use as an oxygen concentrator to provide supplemental low flow oxygen therapy in the home, nursing homes, patient care facilities, etc. The POCA01 is available by prescription only under the supervision of a physician, and is not intended to support or sustain life.

Technological Characteristics:
Technologies utilized by the A&J-POCA01 Oxygen Concentrator bring forth no new questions of safety and effectiveness. These technologies are also currently being used in the identified predicate device.

Bench performance testing has demonstrated that the A&J POCA01 Oxygen

Concentrator is substantially equivalent to the predicate device.

The main different between the A&J-POCA01 Oxygen Concentrator and the Mark 5 Nuvo Oxygen Concentrator are the physical characteristics, such as the dimensions, the weight, the storage conditions, these different would not affect the safety and efficiencies of the A&J-POCA01, also, the power consumption and the oxygen percentage of the A&J-POCA01 are different to the predicate, but these characteristics are better than the predicate. The A&J-POCA01 Oxygen Concentrator is substantially equivalent to the predicate device.

Testing:
Laboratory testing was conducted to validate and verify that the A&J-POCA01 Oxygen Concentrator met all design specifications and was substantially equivalent to the predicate device. This testing consisted of all environmental testing identified in the FDA's DCRND November 1993 "Reviewer Guidance Document for Premarket notification Submissions" Draft Guidance Document. Additional testing was performed to demonstrate compliance with the standards of ASTM F1464 and ISO 8359. Finally, a hazard analysis of the system and its software was performed and testing was conducted to validate the systems overall operation. The A&J POCA01 Oxygen Concentrator has also been tested to assure compliance to the requirements of various published standards, including IEC60601-1, IEC60601-1-2, IEC60601-1-4, and ISO14971.

Conclusion:
The conclusions drawn from the testing of the A&J-POCA01 Oxygen Concentrator demonstrates that the device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2008

Zhongshan A&J Medical Equipment Company, Limited
C/O Ms. Michelle S. Lee
Responsible Third Party Official
Underwriters Laboratories, Incorporated
Laboratory and Testing
2600 NW Lake Road
Camas, Washington 98607-9526

Re: K071608
Trade/Device Name: A&J-POCA01 Oxygen Concentrator
Regulation Number: 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: December 20, 2007
Received: December 28, 2007

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

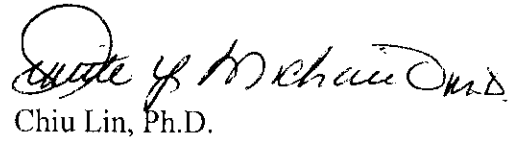
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Chapter 03

510(k) Number (if known): _____

Device Name: A&J-POCA01 Oxygen Concentrator

Indications For Use:

The A&J-POCA01 Oxygen Concentrator is intended for use as an oxygen concentrator to provide supplemental low flow oxygen therapy in the home, nursing homes, patient care facilities, etc. The A&J-POCA01 is available by prescription only under the supervision of a physician, and is not intended to support or sustain life.

Prescription Use X (Per 21 CFR 801 Subpart D)

Over-The Counter Use _____ OR (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K071608